

REMARKS/ARGUMENTS

Status of the Claims

Claims 1-3, 7, 10-18, 28-31, and 34-39 are pending in the present application. Claims 8, and 32 have been cancelled without prejudice to or disclaimer of the subject matter contained therein. Claims 1, 3, 7, 34-36, and 39 have been amended as described elsewhere herein. No new matter has been added by amendment.

The Examiner is respectfully requested to withdraw the rejection and allow claims 1-3, 7, 10-18, 28-31, and 34-39. In any event, the Examiner is requested to enter the above amendments for purposes of further prosecution. These amendments were not made earlier because Applicants earnestly believe that the specification is enabling for the breadth of the claims as originally drafted.

The Rejections Under 35 U.S.C. § 112, First Paragraph, Should be Withdrawn

The Examiner has rejected claims 1-3, 7, 8, 10-13, and 32 under 35 U.S.C. § 112, first paragraph, on the grounds that they lack a sufficient written description. It is respectfully submitted that the rejection should not be applied to the claims as amended for the reasons described below.

The Examiner states that the specification does not provide support for the ligand binding site "set forth as amino acids 4038-4547 of SEQ ID NO:2" as recited in claims 1(f), 7(f), and 32. Applicants acknowledge the error noted by the Examiner; in fact lines 7-8 of page 35 refer to the Cry1A binding site *encoded* by nucleotides 4038-4547 of SEQ ID NO:1. In any case, this language has been deleted from claims 1, 7, and 32 to expedite prosecution as described below, rendering the rejection moot.

The Examiner has further rejected claims 1-3, 7, 8, 10-18, 28, 29, 32, and 34-39 under 35 U.S.C. § 112, first paragraph, on the grounds that polypeptides comprising a fragment of SEQ ID NO:2 as recited in claims are not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed

invention at the time the application was filed. The rejection is respectfully traversed for the reasons described below.

In the Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description," 66 Fed. Reg. 1099 (Jan. 5, 2001), the USPTO states that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant, identifying characteristics, *i.e.* complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of these characteristics." *Id.* at 1106. This standard for the written description requirement set forth in the *Guidelines* was also adopted by the Federal Circuit in *Enzo Biochem, Inc. v. Chugai Pharma U.S.A., Inc.*, 296 F.3d 1316 (Fed. Cir. 2002).

Claims 1-3, 7, 8, 10-18, 28-29, 32, and 34-39 meet the requirements for written description under the *Guidelines* and *Enzo* because they provide the relevant, identifying characteristics, including the partial structure and functional characteristics, of the claimed polypeptides. Claims 1(f), 7(f), and 32 as previously amended encompass only those polypeptides that contain a ligand binding site having the specified sequence and have *Bt* toxin binding activity. The specification provides guidance regarding the ligand binding domain of the ECB *Bt* toxin receptor on lines 5-10 of page 35, and provides examples of assays for *Bt* toxin binding activity on lines 20-29 of page 5 of the specification. Thus, these claims provide the relevant, identifying structural and functional characteristics of the members of each claimed genus of sequences that distinguish them from other sequences. Accordingly, one skilled in the art would be able to determine the identity of the members of the claimed genera, and would recognize that the Applicants were in possession of the claimed invention.

Nevertheless, Applicants have amended claims 1 and 7 and cancelled claim 32 to delete references to polypeptides comprising the ligand binding site of SEQ ID NO:2, thereby obviating the rejection. These amendments are made to expedite prosecution, and this subject matter will be pursued in a continuation application.

In view of the above amendments, all grounds for rejection under 35 U.S.C. § 112, first paragraph, have been overcome. Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

The Rejection Under 35 U.S.C. 112, Second Paragraph, Should be Withdrawn

The rejection of claims 7, 8, and 33-36 under 35 U.S.C. § 112, second paragraph, on the grounds that they are indefinite for reciting "at least one polypeptide of interest" has been maintained. Claim 33 has previously been cancelled, rendering the rejection of this claim moot. The rejection of the remaining claims is respectfully traversed for the reasons described below.

According to the *Manual of Patent Examining Procedure*, the test for the definiteness of a patent claim is "whether 'those skilled in the art would understand what is claimed when the claim is read in light of the specification.'" *Manual of Patent Examining Procedure* § 2173.02 (8th ed. Revision No. 1 Feb. 2003), citing *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). The phrase "polypeptide of interest" as used in claims 7, 8, and 34-36 meets this standard because its meaning would be clear to those of skill in the art when read in light of the supporting specification. The specification states that a fusion polypeptide can be made with the novel receptor of the invention and one or more polypeptides of interest. The specification further provides rationales for selecting a polypeptide of interest for use in a receptor fusion polypeptide. For example, the specification states that a polypeptide of interest may be used to facilitate purification of the novel receptor protein, to provide for secretion of the novel receptor protein, or to alter the membrane localization and/or topology of the novel receptor protein. The specification also provides examples of polypeptides of interest that may be selected to create fusion proteins having the desired properties (see, for example, pages 21-22 of the specification).

Thus, one of skill in the art, reading claims 7, 8, and 34-36 in light of this supporting description, would be able to ascertain that the polypeptide of interest recited in these claims is a polypeptide that could be fused to the novel receptor sequences of the invention to convey a desired property to the fusion polypeptide. There are numerous examples of such polypeptides of interest in the prior art and such polypeptides are well known to those of ordinary skill in the

art. Furthermore, the claims recite only those fusion polypeptides that contain a novel receptor sequence of the invention. Therefore, the metes and bounds of the claim would be readily ascertainable by one of skill in the art.

Nevertheless, the phrase "polypeptide of interest" has been deleted from claims 7, 8, and 34-36. These amendments are made without prejudice solely to expedite prosecution, and the deleted subject matter will be pursued in a continuation application.

In view of the above arguments and amendments, all grounds for the rejection under 35 U.S.C. § 112, second paragraph, have been overcome. Reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSIONS

It is believed that all the rejections have been obviated or overcome and the claims are in condition for allowance. Early notice to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned agent.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

Kathryn L. Coulter
Kathryn L. Coulter
Registration No. 45,889

| | |
|---|---|
| <p>Customer No. 29122 ALSTON & BIRD LLP Bank of America Plaza 101 South Tryon Street, Suite 4000 Charlotte, NC 28280-4000 Tel Raleigh Office (919) 862-2200 Fax Raleigh Office (919) 862-2260</p> | <p>CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on July 29, 2004 <i>Nora C Martinez</i> Nora C. Martinez</p> |
|---|---|